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CERTIFICATE OF COMPLIANCE

DATE: April 15, 2024
SUBJECT: REGULATORY COMPLIANCE FOR VALUE PRODUCTS
PART AFFECTED: ALL TUBING SOLD BY VALUE PLASTICS WITH AN AF PART NUMBER
MATERIAL: ADVANTAFLEX THERMOPLASTIC ELASTOMER
TYPE: NEW AGE INDUSTRIES
SUPPLIER:

Dear Valued Customer,

Thank you for your interest in Nordson MEDICAL's Value Plastics line of products. As part of our continuous improvement initiatives, and to provide the most timely and effective responses possible, we have created this comprehensive list of the most up to date regulatory compliance information available at <https://www.nordsonmedical.com/Components-and-Technologies/Fluid-Management-Components/Support/Material-Information/> and <https://www.nordsonmedical.com/Resources/Regulatory-Compliance>. The information contained herein generally fulfills the bulk of our customers' regulatory requirements, however if there is additional information required that is not provided here, please submit your request to LOV_QA-RA@nordsonmedical.com.

Please be informed that Nordson MEDICAL relies on information provided by our suppliers and vendors, whose materials make up the sole content of our products as there are no processing agents or mold releases used in the manufacture of our products. Nordson MEDICAL does not test or analyze these materials for ANY specified regulatory requirements; the information provided by the resin manufacturers has simply been compiled in a readily retrievable format as a service to our customers. Ultimately customers and end-users must make their own determinations ensuring the use of these products is safe, lawful, and suitable for their intended applications. Because of possible changes in the law and/or in regulations, we encourage our customers to periodically verify the status of the regulatory compliance. These compliance letters are typically updated annually, upon receiving new regulatory information, or as deemed necessary.

Regards,

Brian Benton

Manufacturing and Quality Manager

Nordson Medical

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USE OF THIS REGULATORY INFORMATION						
The information provided as requested is intended to be used for informational purposes only. Nordson MEDICAL relies on information provided by their suppliers or vendors. Nordson MEDICAL makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of compounds under end-use conditions prior to specification is essential. Ultimately, customer+A1:G88s must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.						
ITEM	REGULATORY REQUIREMENTS	COMPLIANT				COMMENTS
		Y	N	N/A	See Comment	
1	Allergens (Global Food)	Y				The manufacturer does not intentionally use allergens in the formulation of this product.
2	ELV Directive 2000/53/EC (Heavy Metal)	Y				The quantity of Pb, Hg, Cd, and Cr present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2002/525/EC of June 27th (amending Annex II of Directive 2000/53) which establishes: 0.1% Pb, 0.1% Cr, 0.1% Hg, and 0.01% Cd.
3	21 CFR 177.2510, 177.2600, 177.1520, 21 CFR 178.3297, 21 CFR 176.170, 21 CFR 177.1500, 21 CFR 177.1580, 21 CFR 177.1520(a)(3)(a) and (c) 3.1a, 21 CFR 177.1550, 21 CFR 177.2470, 21 CFR 177.2480, 21 CFR 177.2600, 21 CFR 177.2600 (Food Contact)	Y				21 CFR 177.1500 (food contact): This material may be used to produce articles or components of articles intended for repeat use in processing, handling, and packaging food, for all food types at temperatures not to exceed 400 degrees F. Medical and pharmaceutical applications are not considered by these regulations. 21 CFR 177.2600 (Food Contact): Supplier has third party certificate of compliance on file
4	3-A Sanitary Standards	Y				Supplier has third party certificate of compliance on file

5	AD-DSL (the AeroSpace & Defence Declarable)				See Comment	AS far as our knowledge this product is Not listed/Not regulated. Although, Nordson does not monitor this list closely, Nordson Medical is focused on Medical Compliance especially to the ISO 13485 Standards. The customer is responsible for verifying this information for themselves.
6	Animal Derived Materials	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
7	Aromatic Amines	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
8	ASTM D3222			N/A		Our Supplier has not indicated if this material meets these standards
9	ASTM F963 Standard Consumer Safety for Toy Safety			N/A		Our Supplier has not indicated if this material meets these standards
10	BioCides	Y				Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
11	Biocompatibility	Y				Components have been tested by the raw material manufacturer under USP Class VI and ISO 10993 standards LISTED BELOW.
12	Bioterrorism Act of 2002			N/A		The facility manufacturing these products not required to register with the Bioterrorism Act of 2002 because it is not a food facility.
13	BISPHENOL A (BPA)	Y				Not used in the manufacture or formulation of this product.
14	BSE/TSE	Y				This material is not manufactured with any animal product and is considered to be free from BSE & TSE.
15	California Prop 65	Y				Based on available information this product does not contain any components or chemicals currently known to the State of California to cause cancer, birth defects or reproductive harm at levels which would be subject to Proposition 65. Reformulation, use, or processing of this material may affect its composition and require re-evaluation.

16	Canadian WHMIS INGREDIENT DISCLOSURE LIST, Canadian Domestic Substance List (DSL), AND OTHER APPLICABLE REGULATIONS	Y				AS far as our knowledge this product is Not listed/Not regulated.
17	Chemicals of High Concern to Children (CHCC) Maine, Vermont, Washington	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
18	China RoHS	y				Based on a review of the final product composition, there are no listed substances known to be present above the reporting threshold.
19	Clean Air Act, 40 CFR	y				To the best of our knowledge this product is not intentionally manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1993, as amended (58 FR 8136).
20	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):	Y				The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.
21	CONEG	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
22	Conflict Minerals	Y				Not intentionally added in the manufacturing of or formulation. Due to the absence of use of these substances, we do not test for them.
23	Consumer Product Safety Improvement Act of 2008 (CPSIA)	Y				To the best of our knowledge This product is not manufactured or formulated with lead, di-(2- ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Our supplier has indicated that it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.
24	Drug Master File			N/A		To the best of our knowledge this Material is not Listed.

25	Endotoxins				See Comment	Please be aware that Value Plastics does not perform endotoxin or bioburden testing on our components. The vast majority of our components are catalog products, and may be used in many applications, therefore we do not test or analyze our materials for any specified regulatory requirements. Ultimately, we leave it to the end-user to make their own determination that our products are safe and suited for their intended applications. However, our processes are highly automated with minimal operator contact, and our production processes don't involve water, so we believe endotoxin levels on our parts to be low.
26	EU 200/53/EC & 2002/525/EC -END-OF-Life Vehicles Regulation			N/A		Our Supplier has not indicated if this material meets these standards
27	EU Commission Decision 2009/251/EC – Dimethylfumarate	y				To the best of our knowledge: This product does not use the biocide Dimethyl fumarate in its formulation or manufacture
28	EU Directive 2002/16/EC			N/A		Our Supplier has not indicated if this material meets these standards
29	EU Directive 2003/11/EC			N/A		Our Supplier has not indicated if this material meets these standards
30	EU Directive 76/769 EEC and Regulation EC 1907/2006 - Hexabromo Cyclododecane (HBCDD) and Hexachlorobenze (HCB) –			N/A		Our Supplier has not indicated if this material meets these standards
31	EU Directive 90/128 and subsequent ammendments			N/A		Our Supplier has not indicated if this material meets these standards
32	EU MDR			N/A		Our Supplier has not indicated if this material meets these standards
33	EU-Food Contact			N/A		Our Supplier has not indicated if this material meets these standards
34	EU-Pharmacopeia (7th Edition)	y				Supplier has third party certificate of compliance on file.
35	European Directive (94/62/EC) (Article 11), (2004/12/EC), and its ammendments Packaging and Packaging Waste			N/A		Our Supplier has not indicated if this material meets these standards
36	European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)			N/A		Our Supplier has not indicated if this material meets these standards

37	Formaldehyde	Y			Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
38	Genetically Modified Organism Free	Y			Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
39	GHS	Y			This mixture is not classified according to US-GHS.
40	Gluten-Free	Y			Not intentionally added in the manufacturing of or formulation of the listed molding compound grades. Due to the absence of use of these substances, we do not test for them.
41	ILFI – Red List Chemicals The International Living Future Institute	Y			Not intentionally added during the manufacture or formulation of this product.
42	In Vitro Hemocompatibility Assay (ISO)	Y			Supplier has third party certificate of compliance on file.
43	International Inventories	Y			AS far as our knowledge this product is Not listed/Not regulated.
44	ISO 10993-1			N/A	This material has not been tested against these standards to our knowledge
45	ISO 10993-10	Y			Supplier has third party certificate of compliance on file.
46	ISO 10993-11	Y			Supplier has third party certificate of compliance on file.
47	ISO 10993-12			N/A	This material has not been tested against these standards to our knowledge
48	ISO 10993-18, EXTRACTABLES TESTING	Y			Supplier has third party certificate of compliance on file.
49	ISO 10993-2			N/A	This material has not been tested against these standards to our knowledge
50	ISO 10993-3	Y			Supplier has third party certificate of compliance on file.
51	ISO 10993-4	Y			Supplier has third party certificate of compliance on file.
52	ISO 10993-5	Y		N/A	Supplier has third party certificate of compliance on file.
53	ISO 10993-6			N/A	This material has not been tested against these standards to our knowledge
54	Kosher		N		Supplier does not certify this resin to be Kosher or in compliance with Kosher requirements

55	Lactose	Y				Not intentionally added during the manufacture or formulation of this product.
56	Latex	Y				Not intentionally added during the manufacture or formulation of this product.
57	MA Right to Know Extraordinarily Hazardous Substance List	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
58	Melamine	Y				Not intentionally used in the manufacture or formulation of this product.
59	Natrual Rubber	Y				Not intentionally added during the manufacture or formulation of this product.
60	Nitrosamines	Y				Not used in the manufacture or formulation of this product.
61	NJ Right to Know Regulated Chemicals	Y				To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
62	Nanoparticles	Y				To the best of our knowledge, the above-mentioned products are not intentionally manufactured or formulated with this compound or substance.
63	NSF 61				See Comment	See https://www.nsf.org/certified-products-systems for reference.
64	NSF-14				See Comment	See https://www.nsf.org/certified-products-systems for reference.
65	NSF-51				See Comment	See https://www.nsf.org/certified-products-systems for reference.
66	Other Substance/compounds				See Comment	The following Material and compounds are Not intentionally used or added in the formulation or manufacture of this product, but due to the nature of these items we do not test for them: Aflatoxin-like compounds, Aldehydes, Ames Assay (ISO), Azoxy Compounds, BPA, Tin, Tantalum, Tungsten, and Gold, Isocyanates, Latex, Natural Rubbers, Melamine, N-Nitrososo Compounds, Organic Phosphates, Phthalates, Radio Active Compounds, 2-Mercaptobenzothiazole, Polyaromatic hydrocarbons, ompounds of cadmium, lead, mercury, and hexavalent chromium, flame retardants PBB and PBDE, including penta- ocat- and decabromodiphenyl ethers, Trisnonylphenylphosphite

67	Ozone Depleting Substances	Y			The manufacturer confirms that these products comply with the requirements of Regulation (EC) 1005/2009 on substance, that deplete the ozone layer.
68	PA Right to Know Regulated Chemicals	Y			To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
69	Persistent Organic Pollutants (POP)	Y			To the best of our knowledge, this product does not contain chemicals at levels which require reporting under this statute.
70	PFAS (Per and Polyfluoroalkyl substances)	Y			Not used in manufacture or formulation of product.
71	PFCA (Perfluoroalkyl carboxylic acid)	Y			Not used in manufacture or formulation of product.
72	PFOA (Perflouroctanoic acid)	Y			Not used in manufacture or formulation of product.
73	PFOS (Perflouroctane sulfonate)	Y			Not used in manufacture or formulation of product.
74	Phthalates: Dibutyl phthalate Dioctyl phthalate (DEHP) Di-isononyl phthalate Dimethyl phthalate DMP CAS# 131-11-3 Diethyl phthalate DEP CAS# 84-66-2 Diallyl phthalate DAP CAS# 131-17-9 Di-n-propyl phthalate DPP CAS# 131-16-8 Di-n-butyl phthalate DBP CAS# 84-74-2 Diisobutyl phthalate DIBP CAS# 84-69-5 Butyl cyclohexyl phthalate BCP CAS# 84-64-0 1,2-bis(2-methoxyethyl) ester DMEP CAS# 117-82-8 [bis(2-methoxyethyl) phthalate] Di-n-pentyl phthalate DNPP CAS# 131-18-0 1,2-Benzenedicarboxylic acid, dipentyl ester branched and linear CAS# 84779-61-3 Dicyclohexyl phthalate DCP CAS# 84-61-7 Butyl benzyl phthalate BBP CAS# 85-68-7	Y			No Phthalates are intentionally added or expected as process impurities above corresponding 0.1% threshold limits.

	Di-n-hexyl phthalate DnHP CAS# 84-75-3				
75	REACH	Y			<p>REACH Substances of Very High Concern (SVHC), as specified according to (EC) 1907/2006 and the Candidate List published by ECHA (European Chemical Agency) on January 17, 2022. The product above contains one or more of the following siloxanes (#184, 187, 190):</p> <ul style="list-style-type: none"> •Octamethylcyclotetrasiloxane (D4) •Decamethylcyclopentasiloxane (D5) •Dodecamethylcyclohexasiloxane (D6) <p>These SVHCs are present at greater than 0.1% by weight. Therefore, REACH compliance is conditional based upon the amount of material imported into the EU.</p>
76	RoHS / RoHS 2 / RoHS 3	Y			<p>The material supplier has declared that this material complies with 2011/65/EC and (EU) 2015/863.</p>
77	SARA (311,312) Hazard Class	Y			<p>AS far as our knowledge this product is Not listed/Not regulated.</p>

78	SARA 313 Regulated Chemicals	Y				This product is not regulated under section 313 Title III of the Superfund Amendments & Reauthorization Act of 1986
79	SARA Title III – Section 302 Extremely Hazardous Chemicals:	Y				AS far as our knowledge this product is Not listed/Not regulated.
80	Transport Classification	Y				Not regulated as hazardous for shipment.
81	TSCA	Y				The components of this material are listed on the EPA/TSCA inventory of chemical substances
82	Unactivated Partial Thromboplastin Time Assay (ISO)	Y				Supplier has third party certificate of compliance on file
83	US Pharmacopoeia Class VI	Y				Supplier has third party certificate of compliance on file
84	USDA			N/A		This material has not been tested against these standards to our knowledge
85	USP 381 (Elastomeric Closures for injection)	Y				Supplier has third party certificate of compliance on file
86	USP 643 (Total Organic Carbon)			N/A		This material has not been tested against these standards to our knowledge
87	USP 661	Y				Supplier has third party certificate of compliance on file
88	USP 85 (Endotoxin)	Y				Supplier has third party certificate of compliance on file
89	USP 88			N/A		This material has not been tested against these standards to our knowledge
90	USP 851 (Static Sorption Study of Phenol)	Y				Supplier has third party certificate of compliance on file
91	USP 87 (L929 MEM Elution)	Y				Supplier has third party certificate of compliance on file
92	Volatile Organic Compounds (VOCs)	Y				Not used in the manufacture or formulation of this product.
93	WEEE	Y				This material complies with the requirements of this directive: Compounds of cadmium, lead, mercury, and hexavalent chromium, flame retardants PBB and PBDE, including penta- ocat- and decabromodiphenyl ethers, have not been intentionally added during the production of this material.